

REMARKS

Claims 1 - 28 are in the application.

Claims 1 – 21 stand rejected under 35 U.S.C. 101 on the grounds that the claimed invention is directed to non-statutory subject matter. Specifically, Claims 1, 14, and 16 recite an "embedded consultant" (i.e., a human being). The Examiner states that

"where a claim is directed to apparatus "attached to" the human body or any part thereof it may be appropriate to make a rejection under 35 U.S.C. 101 with an explanation that, because the claim positively recites a part of the human body, it is directed to non-statutory subject matter."

Applicants respectfully traverse this rejection and request that each of Claims 1 – 21 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Applicants strenuously object to characterization their claims as having an apparatus "attached to" a human body. Rather, in the context of this application, the human body is a consultant who is associated with the claimed reporting-consulting subsystem. Surely the Examiner understands that no part of the claimed invention is physically attached to the body of a physician who is charged with the responsibility of providing consultations to those requesting services through the claimed system. Applicants' specification, at lines 64 – 70, provides an explicit definition for the term 'embedded'. It is quite clear that consultants are associates of the laboratory and an integral component of the testing the reporting process, and wholly dedicated to the provision of laboratory testing services and serve as professionals meeting the needs of test ordering clinicians.

Applicants respectfully submit that the Examiner's rejection is wholly without merit and, as a result, each of Claims 1 – 21 should be passed to issue over the rejection. Such action is earnestly solicited.

Claims 18 and 22 – 28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of use of the term "desirable" in Claim 18 and "remarkable" in Claim 22. The Examiner states that the specification does not provide a standard for ascertaining the definition of these terms and that one of ordinary skill in the art would accordingly not be reasonably apprised of the scope of the invention. Applicants respectfully traverse this rejection and request that each of Claims 18 and 22 – 28 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Applicants submit that the terms 'desirable' and 'remarkable', in the context of a system which is used to obtain and process laboratory results, is crystal clear, especially when teamed with the usage in Applicants' specification. Applicants respectfully direct the Examiner's attention to their specification at lines 330-347, wherein usage of the term "remarkable", is defined as being the result of a comparison of test results with predetermined reference ranges. Regarding the use of the term 'desirable', is clear from the context of Applicants' specification on lines 121 – 134, that desirability is determined by using positive results obtained during a previous round of testing and previously drawn blood samples to accomplish reflective testing. The meaning of these terms 'desirable' and 'remarkable' is clear from the context of Applicants' specification and each of Claims 18 and 22 – 28 should be passed to issue over the Examiner's rejection. Such action is earnestly solicited.

Claims 1, 3, 9, 11, 13, 14, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas Lab-Works web-site dated 2 August, 2002 and in further view of Bladen et al. (US PGPUB 2002/0099586 A1). The Examiner states that Atlas Lab Works shows an order entry subsystem for submitting orders; a laboratory for receiving orders and managing patients; filling the orders and generating test results; a data storage

subsystem for test results; a triage subsystem for comparing test results downloaded from data storage subsystem; the triage subsystem setting an abnormal results flag in the event that the test results are outside a reference range; a reporting-consulting subsystem for receiving results in comparison from the triage subsystem; the reporting-consulting subsystem transmitting processed test results to the person requesting at least one test; and the reporting-consulting subsystem transmitting results bearing an abnormal results flag to an embedded consultant.

Notwithstanding the previous recitation of what the Examiner found with the four corners of Atlas LabWorks, the Examiner admits that Atlas LabWorks does not disclose a consultant or a reporting-consulting subsystem providing at least one template for a suggestion by a consultant to generate a consultative report concerning the test results. For this content the Examiner looks to Bladen. The Examiner states that Bladen discloses a risk assessment system including consultant-selected templates. The Examiner concludes with the argument that it would have been obvious to one of ordinary skill in the art at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to have included consultant-selected templates, in accordance with the teaching of Bladen, in order to allow for the effective reporting of the consultants findings for laboratory results, and to do so readily and easily by a person of ordinary skill in the art with neither undue experimentation, nor risk of unexpected results. Applicants respectfully traverse this rejection and request that Claim 1 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Applicants have reviewed the Atlas LabWorks web-site information relied upon by the Examiner, and note that the Examiner is correct in his statement that Atlas LabWorks does not disclose either a consultant, or a reporting consulting subsystem. Moreover, Bladen does not disclose either of these elements. Bladen discloses a method and system for assessing

compliance with standards and for minimizing risks associated with noncompliance with standards of care. Although it is true that the term 'template' is used in Bladen's specification, Applicants respectfully submit that a simple keyword search of Bladen would show use of the word template without any care being needed to assure that the template has anything to do with the case being considered here. Bladen's template files are intended to accommodate different risk modalities, such as food, and other health and safety questions and to generate assessment manuals. There is nothing in Bladen, or for that matter in Atlas LabWorks, to either teach or suggest, whether separately, or in combination with each other, the use of a human consultant working with a template provided by a reporting-consulting subsystem to produce a consultative report concerning test results obtained from a patient. The fact of the matter is that neither Atlas LabWorks, nor Bladen, or the combination of the two, either teaches or suggests the generation of a consultative report by a human consultant, working with a template for selection by the consultant providing the consultative report. The system in Claim 1 is therefore allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claims 3, 9, 11 and 13 stand rejected over Atlas LabWorks and Bladen as applied to Claim 1, and further, according to the Examiner, Atlas LabWorks including a template provided by a reporting-consulting subsystem, with a reference range being determined as a function of at least one prior recorded test result, and an alert subsystem for establishing a time-based test sequence in the event that patient test results are not entered into a data storage subsystem according to the specified time interval. Also, interpretive data include at least one of patient-specific archival data, generic tabular data, generic graphical data, and patient-specific graphical data. Applicants respectfully traverse this rejection, and request that each Claims 3, 9, 11 and 13 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Applicants respectfully submit that neither Atlas LabWorks, nor Bladen, whether taken singularly, or in combination with each other, either teach or suggest a template having a data source providing data for generating a consultative report. Moreover, there's nothing in Atlas LabWorks and Bladen about reference ranges determined as a function of a prior-recorded test result, an alert subsystem for establishing a time-based test sequence, or interpretive data comprising at least one of the patient's specific data, etc. As a result, each of Claims 3, 9, 11 and 13 are clearly allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claims 14 and 15 stand rejected over Atlas LabWorks, with the Examiner reciting an internet-based order entry subsystem, a data storage subsystem, a triage subsystem, etc., etc. The Examiner admits that Atlas LabWorks does not include providing a template selectable by an embedded consulting physician, and with the consulting physician generating a consultative report. Applicants respectfully traverse this rejection and request that Claims 14 and 15 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

As noted above, Applicants respectfully submit that neither Atlas LabWorks, nor Bladen either teach or suggest a triage subsystem, in a reporting-consulting subsystem, especially a subsystem providing a template selectable by an embedded consulting physician, and with the physician generating a consultative report using the template with a network terminal, with the report being based upon the test results and with the template including at least one data source for providing data for generating a report. None of these features is found either within the four corners of Atlas LabWorks, or Bladen, nor are they taught, suggested, urged, or disclosed by either of the cited references, or their combination. As a result, Claims 14 and 15 are clearly

allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claims 2, 4, 5, 12, 22, 26 and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas LabWorks in view of Bladen and Edelson et al. (US 5,737,539 A). The Examiner admits that Atlas LabWorks and Bladen do not disclose a data source for providing interpretive data; a computer-linked source of additional information for use by an embedded consultant for generating a consultative report; a computer-linked source of additional information which is internet-based; and a template incorporating interpretive data for use by the embedded consultant in the event that test results require additional analysis. The Examiner states that Edelson discloses a prescription creation system which includes providing interpretive data over the internet. The Examiner argues that it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen to provide a source to have included the provision of interpretative data over the internet in accordance with the teaching of Edelson, with the argument that so doing could be performed readily and easily by any person of ordinary skill in the art with neither undue experimentation, nor risk of unexpected results. Applicants respectfully traverse this rejection and request that each of Claims 2, 4, 5 and 12 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Applicants respectfully submit that the Examiner's addition of Edelson to the combination of Atlas LabWorks and Bladen is to no avail because Edelson teaches nothing more than a system for providing prescriptive information to doctors to allow them to specify a correct drug for a patient. Edelson, whether taken singularly, or in a combination with either Atlas LabWorks or Bladen, or both, neither teaches nor suggests anything regarding the examination

of patient data with an eye to generation of a consultative report by means of an embedded consultant. As a result, Claims 2, 4, 5 and 12 are allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claim 22 stands rejected over Atlas LabWorks, Bladen, and Edelson on the grounds that Edelson provides an internet link with diagnostic information. Although Edelson does contemplate use of the internet to provide information, as noted above, neither Atlas LabWorks, nor Bladen, nor Edelson either teaches or suggests anything regarding the use of a template specified by an embedded consultant providing a consultative report. As a result, Claim 22 should be passed to issue over the Examiner's rejection.

Claims 26 and 27 stand rejected over Atlas LabWorks, Bladen, and Edelson. Claims 26 and 27 depend from Claim 22, which recites the previously described triage subsystem and embedded consultant, and which is allowable for the reasons cited. As a result, Claims 26 and 27 are allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claim 28 stands rejected over Atlas LabWorks, Bladen, and Edelson, and further in view of Ross US 5,823,948 A. The Examiner utilizes Ross for its recitation of data organization in a format that facilitates CPT coding.

Applicants respectfully submit that Claim 28 is allowable over the rejection because neither Atlas LabWorks nor Bladen nor Edelson nor Ross neither teaches or suggests a billing routine, applied to Applicants' system for providing clinical laboratory services, including an invoice bearing an AMA CPT code. Although Ross discusses CPT coding, there is nothing in Ross to teach or suggest that an invoice is provided with such a code. Moreover, Claim 28 depends from Claim 22 which is allowable for the previously described reasons and Claim 28

should therefore be passed to issue over the Examiner's rejection. Such action is earnestly solicited.

Claims 6, 7 and 8 stand rejected over Atlas LabWorks and Bladen, and further in view of Dworkin. The Examiner uses Dworkin for a conferencing subsystem for scheduling a conference between a test requester and the embedded consultant, including a computer net meeting and the scheduling of the net meeting. Applicants note that although Dworkin teaches a conferencing system, Dworkin provides none of the detail missing from the earlier rejections and as a result, Claims 6, 7 and 8, all which depend from Claim 1, are allowable and should be passed to issue. Such action is earnestly solicited.

Claim 10 stands rejected over Atlas Medical in view of Bladen, and further in view of Matsuoka US 5,819,242 A. The Examiner utilizes Matsuoka for the limitation of uploading previous test results for a number of patients, and a subroutine for predicting future test results based at least in part upon the stored test results.

Applicants respectfully traverse the rejection of Claim 10 and request that Claim 10 be reconsidered in view of these remarks and passed to issue over the Examiner's rejection.

Matsuoka discloses a fuzzy logic network, and nothing more regarding the invention set forth in Claim 1, from which Claim 10 depends, and as a result Claim 10 is allowable over the Examiner's rejection and should be passed to issue.

Claims 16 and 18 stand rejected over Atlas LabWorks in view of Bladen, and further in view of Smith US PGPUB 2003/0069749 A1. The Examiner incorporates Smith for its teaching of communicating laboratory test results and the like over the internet. Smith, however, whether taken singularly, or in combination with Atlas LabWorks and Bladen, neither teaches nor suggests Applicants claimed invention as set forth in Claims 16, because as noted above, neither

Atlas LabWorks nor Bladen, nor for that matter, Smith, either teaches or suggests, urges or discloses using a network to cause laboratory test results to be transmitted directly to the test requester in the event test results are within a reference range, while causing the test results to be transmitted by a networked terminal device to a consulting physician via a consultative reporting-consulting subsystem in the event that the test results are outside the reference range, while using results lying outside of the reference range in the reporting-consulting subsystem to provide at least one selectable report template, and using the report template and a consulting physician to generate a consultative report, which is communicated with an electronic signature to the test requester. None of this is found within Atlas LabWorks or Bladen, or Smith, or any teaching or suggestion or urging or disclosure of any of the references, and as a result, Claim 16 is allowable over the Examiner's rejection and should be passed to issue. Such action is earnestly solicited.

Claim 18 stands rejected on the same basis of Claim 16, with the Examiner's additional assertion that Atlas LabWorks discloses requesting performing additional reflective tests. Applicants respectfully submit however, that there is nothing in the Atlas LabWorks disclosure which indicates anything regarding reflective testing, and as a result, Claim 18 is allowable over the Examiner's rejection and should be passed to issue.

Claim 17 stands rejected on the same basis as Claim 16, namely over the combination of Atlas/Bladen/Smith, with the addition of Edelson for an importable additional data source providing test result driven data for generating a consultative report. Edelson, however, describes nothing regarding consultative reporting, and as a result, the combination of Atlas/Bladen/Smith and Edelson, whether taken singularly, or in combination of each other,

cannot comprise a colorable basis for rejection of Claim 17, and this claim, too, should be passed to issue over the Examiner's rejection.

Claims 19 and 20 stand rejected over Atlas/Bladen/Smith and Dworkin. Once again, Dworkin is used for a conferencing system. However, because Dworkin teaches nothing regarding the basics of the system other than conferencing, Claims 19 and 20, also, are allowable over the Examiner's rejection and should be passed to issue.

Claim 21 stands rejected over Atlas in view of Bladen, Smith, and Ross. Ross is cited for a billing of the patient's insurer for time expended by the physician to analyze the test results to draft a consultative report. However, Ross discloses nothing regarding any specific billing activity and is totally devoid of any information which could support the rejection of Claim 21, which is therefore allowable over the Examiner's rejection.

Finally, Claims 23, 24 and 25 stand rejected over Atlas/Bladen/Edelson/Smith. The Examiner uses Smith for a consultant's electronic signature, and for a digital signature. However, as noted above, Smith is totally devoid of any teaching of a consultative embedded system using templates to produce a consultative report which is provided to a primary care physician, and as a result, Claims 23, 24 and 25 are clearly allowable over the Examiner's rejection.

In summary, each of the claims in this case, i.e., Claims 1 – 28 is clearly allowable over the Examiner's various rejections and should be passed to issue at this time. Such action is earnestly solicited.

Concluding Remarks

Reconsideration of this application as amended is respectfully requested.

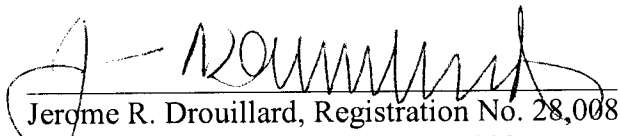
It is believed that this application is now in condition for allowance. Further and favorable action is requested.

The Patent Office is authorized to charge any fee deficiency or refund any excess to Deposit Account No. 04-1061.

Respectfully submitted,

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